

## **NDA 22-253 VIMPAT (LACOSAMIDE) TABLETS NDA 22-254 VIMPAT (LACOSAMIDE) INJECTION**

### **PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

#### **I. GOAL**

The goal of this REMS is to communicate the risks of VIMPAT.

#### **II. REMS ELEMENTS**

##### **A. Medication Guide**

A Medication Guide will be dispensed with each VIMPAT prescription. UCB will assure that MedGuides are provided with each order in sufficient quantity to assure that a MedGuide is available at the time of dispensing to the patient. As printed materials, MedGuides will be controlled using appropriate techniques (ie. barcoding) to assure that the correct Medguide is provided with each order that UCB fills.

Because the medication guide is included as part of the secondary package for VIMPAT, UCB has met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

##### **B. Communication Plan**

The REMS for VIMPAT does not include a Communication Plan.

##### **C. Elements to Assure Safe Use**

This REMS for VIMPAT does not include elements to assure safe use.

##### **D. Implementation System**

Because this REMS for VIMPAT does not include elements to assure safe use, and implementation system is not required.

#### **III. ASSESSMENT OF REMS**

The Timetable for Assessments is as follows:

1<sup>st</sup> FDAAA assessment: April 2010 (18 months from approval)

2<sup>nd</sup> FDAAA assessment: October 2011 (3 years from approval)

3<sup>rd</sup> FDAAA assessment: October 2015 (7 years from approval)

UCB will submit the assessments within 60 days of the close of the intervals as noted above.